The One Norm Every Manufacturer Of Disinfectants In Europe Should Know - EN 14885:2015

A transparent and fixed standard applied across the board allows false claims to be proven swiftly and the perpetrators brought to justice.

The primary purpose of a disinfectant is to reduce the number of microorganisms on an instrument or surface to render them safe for re-use. One of the reasons manufacturers of disinfectants advertise a long list of antimicrobial claims is to outnumber the claims of competitors and prove the superiority of their products. In medical settings however, these claims can be a matter of life and death and as such must be supported by independent laboratory tests.

In Europe, the process of qualifying a disinfectant intended for use in the area of human medicine, veterinary or food, industrial, domestic and institutional areas is guided by EN 14885:2015. At present, the standard is applicable to products for which activity is claimed against vegetative bacteria, bacterial spores, mycobacterium, yeasts, fungal spores and viruses including bacteriophages.

The norm lists basic laboratory tests chemical disinfectants must pass to validate antimicrobial claims by manufacturers including test methods, specific test microorganisms, test conditions and log reduction requirements. To illustrate this better, let's take instrument disinfectants as an example.

Instrument disinfectants

According to EN 14885:2015, all instrument disinfectants intended for use in the medical area must pass the following bactericidal and yeasticidal activity tests to meet the minimum requirements.

Bactericidal activity tests - EN 13727: Quantitative suspension test for the evaluation of bactericidal activity in the medical area (Phase 2, Step 1) and EN 14561: Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (Phase 2, Step 2).

Yeasticidal activity tests - EN 13624: Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area (Phase 2 Step 1), EN 14562: Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area (Phase 2, Step 2).

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EN 14885:2015 further states that to pass EN 13727 (Phase 2, Step 1) suspension test, the test product must be tested against Staphylococcus aureus, Pseudomonas aeruginosa and Enterococcus hirae between the temperatures of 20°C (obligatory) and 70°C and Enterococcus faecium when the temperature is 40°C or higher. The product must demonstrate the ability to reduce the number of each type of microorganism by 100,000-fold known as 5-log reduction within 60 minutes in clean or dirty conditions. To simulate clean conditions, bovine serum albumin (BSA) is added into the suspension. BSA is a type of protein derived from cows and it is typically used as a standard protein in microbiological tests due to its stability. To simulate dirty conditions, BSA and sheep blood is added into the suspension.

In EN 14561 (Phase 2, Step 2), the test product is tested in the same conditions as above using a glass slide as a carrier of test bacteria, which is why it is commonly known as a carrier test. Once again, as above, the test product must demonstrate the ability to achieve 5 log reduction within 60 minutes or less at 20° C.

If the test product passes both these tests, it is accepted as active against all bacteria and as such entitled to make bactericidal claim. However, this single claim is not sufficient if the product is to be sold in the European Union. It must pass yeasticidal activity test as well.

EN 13624 (Phase 2 Step 1) is a suspension test similar to EN 13727 (Phase 2, Step 1). However, there are 2 significant differences:

The test microorganism is substituted with Candida albicans, a common yeast

The test product must demonstrate the ability to achieve 4 log reduction of C. albicans in 60 minutes

EN 14562 (Phase 2, Step 2) is a carrier test similar to EN 14561 (Phase 2, Step 2). As you may have already guessed, the test microorganism here is substituted with Candida albicans to represent yeasts and it must achieve 4 log reduction.

Upon passing all four tests, the test product is deemed to have met the minimum requirements of EN 14885:2015 and as such eligible for sale in the EU.

One point to note here is, although the standard lists the minimum requirements, each area of application also has additional European standards a product can be tested against. Instrument disinfectants for example, can be tested for fungicidal, tuberculocidal / mycobactericidal, limited and fully virucidal or sporicidal activity. At Viroxy, we encourage our clients to consider adding these suggested tests to make additional claims. When we consider the dangers that viruses and mycobacteria pose in medical settings, the onus is on manufacturers to develop products that exceed the minimum requirements.

It is important to remember that EN 14885:2015 has established different requirements, tests and pass criteria for different areas of application (i.e medical and veterinary) to address the challenges of each area effectively.

We highly recommend manufacturers to refer to the original version of EN 14885:2015 by the European Committee for Standardisation prior to deciding on the appropriate test standards to support product antimicrobial claims.

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Why is EN 14885:2015 important?

1. Simulates actual conditions

EN 14885:2015 outlines a 3-phase test method where the test conditions come closer to resembling actual settings with each phase. Phase 1 tests are basic quantitative suspension tests to establish that the active ingredients in a disinfectant have antimicrobial properties without considering specific areas of application. Phase 2 is sub-divided into step 1 and step 2 to test the product's antimicrobial capabilities under simulated conditions. Phase 3 is a field test, conducted under real conditions and extend over a period of time. It is important to note here that the result from phase 1 test conducted outside the actual area of application cannot be used for efficacy claim.

2. Provides manufacturers a point of reference

The norm outlines the most basic of disinfectant tests to enable manufacturers to select the appropriate standards to meet minimum requirements and validate claims. Astute manufacturers usually procure tests beyond the scope of EN 14885:2015 and sometimes beyond European standards to inflate product capabilities. This way, the product is able to compete in markets outside the European Union and it is well recommended as long as the product meets basic requirements.

3. Enables end-users to assess products

A product tested according to standard tests, validated and clearly labelled as such will enable users to assess the suitability of a product for their intended use. For example, a surface disinfectant meant to disinfect surfaces in a hospital may not be appropriate to disinfect surfaces in a veterinary hospital. Each area of disinfection has specific requirements and employ different disinfection methodologies as outlined in EN 14885:2015.

4. Helps regulatory authorities in validating claims made by manufacturers

The standards set in EN 14885:2015 make it easier for regulatory authorities to verify the claims made by a manufacturer. A transparent and fixed standard applied across the board provides little room for error and does not leave definition to terms such as bactericidal, virucidal, sporicidal etc. open to interpretation or debate. False claims can be proven swiftly and the perpetrators brought to justice.

We highly recommend manufacturers to refer to EN 14885:2015 test methods by the European Committee for Standardisation when deciding on the appropriate test standards to support product antimicrobial claims.

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